



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 11 1999

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The Honorable Jeff Sessions
United State Senate
Washington, D.C. 20510-0104

Dear Senator Sessions:

Thank you for your letter of April 21, 1999 concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA) by the Center for Science in the Public Interest. As you know, FDA published a request for comments on this petition in the *Federal Register* of January 21, 1999.

You provided several reasons why you believe adoption of this proposal would have an adverse economic impact on the oyster industry. You urge FDA to let the market determine the need for increased post treatment of oysters and let consumers retain their right to choose.

Thank you for your thoughtful comments. We have entered them into the Administrative Record for this petition and they will be considered in the Agency's deliberations on this petition.

Please contact us if we may be of further assistance in this matter.

Sincerely,


Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: Documents Management Branch
(Docket No 98P-0504)

98P-0504

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United States Senate

WASHINGTON, DC 20510-0104

April 21, 1999

Honorable Dr. Jane Henney
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

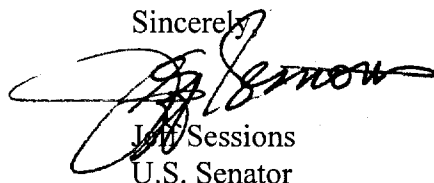
Dear Dr. Henney,

As you consider the citizen's petition presented to you by the Center for Science in the Public Interest regarding the consumption of raw oysters, I urge you to carefully weigh the consequences of moving forward with a proposed rule making which might require the post harvest treatment of fresh oysters.

Raw oysters have been consumed by the public for generations with few incidences of serious sickness caused by the vibrio vulnificus bacteria and then only to a relatively small "at risk" population subgroup. In order to protect this "at risk" population, the oyster industry has been engaged in an impressive public awareness campaign to help inform the public of the risks the vibrio vulnificus bacteria can pose to the small at risk population. For nearly 15 years the industry has implemented this independent regulatory approach through a memorandum of understanding between the Interstate Shellfish Sanitation Commission and the Food and Drug Administration. By all counts, this arrangement has been very successful in reducing the number of serious illnesses and deaths from exposure to vibrio vulnificus.

If post harvest treatment of fresh oysters is forced upon the oyster industry, oyster harvesters contend that it will effectively double the price of oysters forcing a reduction in consumer demand and may drive many oyster harvesters out of business. In addition, post treatment options currently available for oysters cause the taste and texture of raw oysters to deteriorate and will undoubtedly contribute to decreased demand. If consumer demand for treated oysters increases then surely the market will respond by making treated oysters more readily available, giving consumers the option to choose between treated and untreated oysters. I urge you to let the market determine the need for increased post treatment of oysters and let consumers retain their right to choose.

Sincerely,



Jeff Sessions
U.S. Senator

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